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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/821,654 | 03/29/2001 | Kenichi Hosoya | 10939/2012 | 6149 |

29932 7590 02/17/2004

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| EXAMINER |
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SULLIVAN, DANIEL M

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,654

Applicant(s)

HOSOYA ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 November 2003 has been entered.

Claims 1-14 are pending and under consideration.

Response to Arguments

Claim Rejections - 35 USC § 112

Rejection of claims 1-14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is withdrawn in view of the arguments set forth in the 25 November Paper.

New Grounds

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon applications filed in Japan on 2 October 1998 and an international application filed 1 October 1999. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said

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application, since the United States application was filed more than twelve months thereafter.

The declaration and Application Data sheet indicate that the instant application claims benefit of international application PCT/JP99/05423 and Japanese applications 296138 and 296139 under 35 U.S.C. §119. However, the claim is improper because the instant application was filed more than 12 months after the priority applications.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Although the declaration filed 1 June 2003 indicates that the instant application claims benefit of PCT/JP99/05423 under 35 U.S.C. §120, the required reference is absent from the specification or Application Data Sheet. The filing of a corrected Application Data Sheet properly claiming benefit of the international application under 35 U.S.C. §120 would be sufficient to establish priority to PCT/JP99/05423 under 35 U.S.C. §120 and to the Japanese applications under 35 U.S.C. §119(a)-(d).

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5, 7, 9, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 7 and 11 are indefinite because they recite limitations as derivatives of some starting material (e.g., a cell derived from retinal capillary endothelial cells). Without a clear statement of the process by which the starting material is derivatized it is not possible to know the metes and bounds of such a limitation because any given starting material can have many divergent derivatives depending on the process of derivatization. Amending the claim to recite, for example, "An established cell established from..." would overcome this rejection.

Claims 5, 9 and 13 are indefinite in failing to set forth a terminal process step that clearly relates back to the preamble. For example, claim 5 is directed to a method of establishing a conditionally immortalized cell, while the terminal process step makes no mention of conditionally immortalized cells. It is therefore unclear whether the use set forth in the preamble requires additional process steps that are not set forth in the body of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Hosoya et al. (2001; Exp. Eye Research, vol. 72, 163-172; previously made of record).

Hosoya et al. (2001) teach the immortalized cell which expresses a temperature sensitive SV40 large T-antigen gene, GLUT-I transporter and p-glycoprotein derived from the retinal capillary endothelial cells of a transgenic rat into which a large T-antigen gene of SV40 temperature sensitive mutant tsA58 has been introduced. In particular, Hosoya et al. teach the TR-iBRB2 cells of the instant invention (see abstract, page 163). Further, in the first full paragraph in the right column on page 164, Hosoya et al. teaches that the cells were established from an animal that was made by injection of BamHI DNA fragments of SV 40 A58 mutant DNA. Thus, the cells of Hosoya *et al.* do not contain a heterologous antibiotic resistance gene according to the limitations of the instant claims. This rejection can be overcome by perfecting the priority claim under 35 U.S.C. §120 as described above.

Claims 7-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Kitazawa et al. (2001; Pharmaceutical Research, vol. 18, no. 1, pp16-22; previously made of record).

Kitazawa et al. (2001) teach the immortalized cell which expresses a temperature sensitive SV40 large T-antigen gene, and shows localization of Na⁺-K⁺ ATPase and GLUT-I transporter in the cell membrane and shows localization of the Na⁺-K⁺ ATPase in the apical side when cultured in a monolayer. Kitazawa et al. teach this cell as derived from choroid plexus epithelial cells of a transgenic rat into which a large T- antigen gene of SV40 temperature sensitive mutant tsA58 has been introduced. In particular, Kitazawa et al. teach the TR-CSFBI

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through TR-CSFBS of the instant invention (see abstract, page 16). Further, in the paragraph bridging pages 16-17, Kitazawa *et al.* teaches that the cells were established from an animal that was made by injection of BamHI DNA fragments of SV 40 A58 mutant DNA. Thus, the cells of Kitazawa *et al.* do not contain a heterologous antibiotic resistance gene according to the limitations of the instant claims. This rejection can be overcome by perfecting the priority claim under 35 U.S.C. §120 as described above.

Claims 11-14 are rejected under 102(a) as being anticipated by Hosoya *et al.* (2000; Journal of Drug Targeting, vol. 8, no. 6, pp 357-370; previously made of record).

Hosoya *et al.* (2000) teach the immortalized cell lines that express GLUT-I transporter, p-glycoprotein, alkaline phosphatase and γ -glutamyltransferase which cell lines were derived from brain capillary endothelial cells of a transgenic rat into which a large T-antigen gene of SV40 temperature sensitive mutant tsA58 has been introduced. In particular, Hosoya *et al.* (2000) teach the TR-BBB cell lines 1, 5, 6, 11, 13 of the instant invention. Further, in the second full paragraph in the right column on page 358, Hosoya *et al.* teaches that the cells were established from an animal that was made by injection of BamHI DNA fragments of SV 40 A58 mutant DNA. Thus, the cells of Hosoya *et al.* do not contain a heterologous antibiotic resistance gene according to the limitations of the instant claims. This rejection can be overcome by perfecting the priority claim under 35 U.S.C. §120 as described above.

Conclusion

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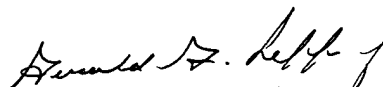
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DMS


GERRY LEFFERS
PRIMARY EXAMINER